guidance is in the form of an annex to the core ICH Q4B guidance made available in the **Federal Register** of February 21, 2008 (73 FR 9575). Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*, *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: July 9, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–17485 Filed 7–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development Special Emphasis Panel, July 16, 2010, 10 a.m. to July 16, 2010, 12 p.m., National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on June 28, 2010, 75 FR 36662.

The date of the meeting has been changed from July 16, 2010 to August 9, 2010. The meeting is closed to the public.

Dated: *July 12, 2010.*

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17567 Filed 7–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus With Onset in Childhood and Adolescence, RFA DP 10–001, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1 p.m.–2:30 p.m., August 3, 2010 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of "Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus with Onset in Childhood and Adolescence, RFA DP 10–001."

Contact Person for More Information: Donald Blackman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, GA 30341, Telephone: (770) 488–3023, E-mail: *DBY7@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 13, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–17562 Filed 7–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, the Department of Health and Human Services is hereby giving notice that the Advisory Commission on Childhood Vaccines (ACCV) will hold a special meeting, to be held by teleconference. This meeting will be equivalent to an in-person meeting and will be open to the public.

Date and Time: The ACCV will meet on Thursday, July 29 from 1 p.m. to 2 p.m. (ET). The public can join the meeting via audio conference call by dialing 1–888–606–5950 on July 29 at 1 pm and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: This is a special meeting of the ACCV. Discussions will surround the draft interim influenza vaccine information materials developed by the Centers for Disease Control and Prevention (CDC) for distribution during the 2010–2011 season by health care providers in the United States to all seasonal influenza vaccine recipients (or to parents or legal representatives in certain cases). For this special meeting, members of the public are invited to attend by teleconference via a toll-free call-in phone number.

SUPPLEMENTARY INFORMATION: Section 2126 of the Public Health Service Act, as amended, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any person (or to parents or legal representatives in certain cases) receiving vaccines covered under the VICP.

Development and revision of vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the CDC. Section 2126 requires that the